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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,399	07/25/2003	Manne Satyanarayana Reddy	BULK 3.0-021	2853
45776	7590	01/24/2005	EXAMINER	
DR. REDDY'S LABORATORIES, INC. 200 SOMERSET CORPORATE BLVD SEVENTH FLOOR, BRIDGEWATER, NJ 08807-2862			SHIAO, REI TSANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,399

Applicant(s)

REDDY ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on application filed on 07/25/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application, INDIA 594/MAS/2002 with a filing date 08/12/1999. However, a certified copy of the priority document has not been received. Therefore, the priority has not been granted. Applicants are request to file the foreign priority document to the Office.
2. Claims 1-18 are pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, line 3, recites the limitation "Figure (1)", fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims must stand alone to define invention, and incorporation into claims by express reference to specification is not permitted, are properly rejected under 35 U.S.C. 112, second paragraph, see *Ex parte Fressola*, No. 93-0828. Incorporation of the values of X-ray powder diffraction of the amorphous form of sumatriptan succinate into the claim would obviate the rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterborn et al. EP 0496307 A1 in view of Crisp et al. US 4,820,833 or Cheronis's publication, "Semimicro Experimental Organic Chemistry", 1958, Chapter 5.

Applicants claim an amorphous form of a compound 3-[2-dimethylamino) ethyl]-N-methyl-1H-Indole-5-methane sulfonamide succinate (Sumatriptan succinate), and its process of making using solvent alcohol or nitrile. The instant amorphous form of Sumatriptan succinate and its processes are found on the pages 1-9 of the specification.

Determination of the scope and content of the prior art (MPEP §2141.01)

Winterborn et al. disclose 3-[2-dimethylamino) ethyl]-N-methyl-1H-Indole-5-methane sulfonamide succinate salt, i.e., Sumatriptan succinate, see page 2, lines 4-15, and Example 3-6 on pages 3-4.

Determination of the difference between the prior art and the claims (MPEP

§2141.02)

The difference between the instant claims and Winterbornet al. is that Winterbornet al. silence the amorphous or crystalline form of the instant compound.

Crisp et al. disclose a process of purification of a compound in a highly pure amorphous form using various solvent, i.e., alcohol, nitrile or water, see columns 2-3, and 4, lines 15-18, 33-56. Crisp et al. amorphous form of compounds has better bio-livability than its crystal form, see columns 2-4.

Cheronis disclose a process of purification of solids compounds by crystallization.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1-18 prima facie obvious **because** one would be motivated to employ the same compound of Winterbornet al. and Crisp et al. or Cheronis's teachings to obtain amorphous forms of Sumatriptan succinate. It is noted that the amorphous or crystalline forms are an innate nature or products of a process of purification in various conditions (i.e., solvent), also see Winterbornet al. '833, column 4, lines 52-56. The skill of purification in choosing proper solvent, temperature and concentration so that amorphous or crystals form is empirical skill well taught and recognized conventionally in the chemical art (see Cheronis's Laboratory manual, chapter 5) or Crisp et al. processes. The employment of a conventional obvious modification for a known compounds and process to obtain an

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instant pure amorphous form is considered prima facie obvious in the absence of unexpected results.

It has long been the practice in the chemical and pharmaceutical arts to produce compounds in the form of amorphous or crystals to secure a pure and stable product. There is no patentable distinction in the concept of a chemical compound in amorphous or crystalline form over the same compound, i.e., Winterborn et al. compounds, see *In re Weijlard*, 69 U.S.P.Q. 86, 87 (C.C.P.A. 1946). Further, changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art, see *In re Cofer*, 148 U.S.P.Q. 268 (CCPA 1966).

The motivation to make the claimed an amorphous form of known pharmaceutically useful compounds derives from the expectation of obtaining a pharmaceutically useful benefit, such as longer shelf life, stability, enhanced deliverability, etc. Therefore, absent a showing of unobvious and superior properties, the instant claimed amorphous forms of known compounds would have been suggested to one skilled in the art.

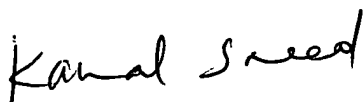
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

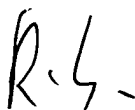
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kamal Saeed
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Robert Shiao, Ph.D.
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January 12, 2005